

Tools and Services for Designing Methodologically Rigorous Animal Studies (R43/R44)

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The official link for this solicitation is: <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-16-003.html>

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Department of Health and Human Services

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Description:

Animal studies play a vital role in science. In scientific research, laboratory animals are used to develop and test putative medications, to elucidate normal biological processes, and to study genes/mutations found in both animals and humans, among others. National Institutes of Health (NIH) is diligent in following the guidelines for ethical conduct in the care and use of animal in research. Finding the appropriate balance between the goals of minimizing the use of animals in research and utilizing the sufficient number of animals in the adequately powered experiments is the task requiring stellar knowledge of the experimental study design and statistics. Unfortunately, the current reality is that in the US many graduate students (and others who are receiving training in the life sciences) receive little formal instruction in experimental design and variable training in statistics. Although some statistical packages (SPSS, SAS, Epi-6) are commercially available, their use without practical understanding of animal study design and methodological rigor is often inappropriate and misguided. While life scientists are advised to seek assistance of professional statisticians at their home institutions, this professional help is often not available or easily accessible.

The purpose of this FOA is to encourage Small Business Concerns (SBCs) to submit applications to create and develop the tools and services that will guide and assist scientists to properly design animal studies. It is understood that the tools/services produced as the result of this FOA are not

intended to fully replace critical thinking and years of scientific training. It is likely that to address the goals of this FOA, the proposed solutions, tools and/or services will be multi-modular in nature. To be responsive to this FOA, the applications must be focused on concurrently addressing the three following technical parameters in the applications: 1) The proposed tools/services must allow for personalized (e.g., face-to-face, on-line chat) access to the professional statisticians and experimental design professionals, preferably, in real time; 2) The proposed tools/services must be, at least, based on the core set of research parameters/reporting standards as described in Nature, 490,187-191, 11 October 2012 see:

<http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>; 3) The proposed tools/services must be designed to inform the sustainable implementation from the start.

The availability, assistance and participation of highly trained statistical staff in experimental designs is universally accepted as imperative; however, this type of support is not commonly available or accessible. Thus, the personal technical assistance element of the proposals submitted in response to this FOA is required. The SBC-applicants will be responsible for the designing the knowledge-based experimental design element of the overall tool/service. Overall, the thorough curation of the relevant literature by the applicant is expected.

Research projects responsive to the goals of this FOA include, but are not limited to, the research and development of the bundled service, including a subscription to on-line software for animal study design with user-friendly and readily accessible web interface (e.g., Module 1: Experimental Design Module), and “real time” access to additional technical/professional support (e.g., Module 2: Personal Assistance Module). The sustainability of such SBIR project could be assured and exemplified by providing access to this bundled service utilizing Software as a Service (SaaS) model. SaaS allows organizations to access business functionality with the pricing based on a monthly fee. Because the software is hosted remotely, users don't need to invest in additional hardware. For example, upon implementation by successful SBC, the customer (a life science researcher from academia or industry) would purchase SBC's bundled service to generate a proper in vivo study design and to obtain a certificate of service assurance. Models different from SaaS models can be proposed as long as it assures sustainable implementation. The support for tool/service design for sustainable implementation from the start emphasis reflects NIDA's desire to contribute its funding to projects resulting in commercialization. To ensure that the developed product or service reaches the market and is successfully disseminated into the scientific community, the applicants are encouraged to complete necessary due diligence, identify the best business development model for commercialization and perform all relevant work to develop a strong value proposition.

Special Considerations

HIV/AIDS Counseling and Testing Policy for the National Institute on Drug Abuse: In light of recent significant advances in rapid testing for HIV and in effective treatments for HIV, NIDA has revised its 2001 policy on HIV counseling and testing. NIDA-funded researchers are strongly encouraged to provide and/or refer research subjects to HIV risk reduction education and education about the benefits of HIV treatment, counseling and testing, referral to treatment, and other appropriate interventions to prevent acquisition and transmission of HIV. This policy applies to all NIDA funded research conducted domestically or internationally. For more information see <http://grants.nih.gov/grants/guide/notice-files/NOT-DA-07-013.html>

National Advisory Council on Drug Abuse Recommended Guidelines for the Administration of Drugs to Human Subjects: The National Advisory Council on Drug Abuse (NACDA) recognizes the importance of research involving the administration of drugs with abuse potential, and dependence or addiction liability, to human subjects. Potential applicants are encouraged to obtain and review these recommendations of Council before submitting an application that will administer compounds to human subjects. The guidelines are available on NIDA's Web site at <http://www.drugabuse.gov/funding/clinical-research/nacda-guidelines-administration-drugs-to-human-subjects>.

Points to Consider Regarding Tobacco Industry Funding of NIDA Applicants: The National Advisory Council on Drug Abuse (NACDA) encourages NIDA and its grantees to consider the points it has set forth with regard to existing or prospective sponsored research agreements with tobacco companies

or their related entities and the impact of acceptance of tobacco industry funding on NIDA's credibility and reputation within the scientific community. Please see <http://www.drugabuse.gov/about-nida/advisory-boards-groups/national-advisory-council-drug-abuse-nacda/council-statements/points-to-consider-regarding-> for details.

Data Harmonization for Substance Abuse and Addiction via the PhenX Toolkit: NIDA strongly encourages investigators involved in human-subjects studies to employ a common set of tools and resources that will promote the collection of comparable data across studies and to do so by incorporating the measures from the Core and Specialty collections, which are available in the Substance Abuse and Addiction Collection of the PhenX Toolkit (www.phenxtoolkit.org). Please see [NOT-DA-12-008](#) for further details.